UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,625	02/01/2001	Jana Sawynok	DALHO1290-1	7582

7590 05/21/2002

STEPHEN E. REITER
FOLEY& LARDNER
P. O. BOX 80278
SAN DIEGO, CA 92138

EXAMINER
WARE, TODD

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/21/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,625	SAWYNOK ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,37-44 and 49-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,37-44 and 49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time, amendment and change of address filed 2-22-02 and information disclosure statement filed 4-16-02 is acknowledged. Claims 26, 42-43, and 53 have been amended and claims 27-36, 45-48, and 63-71 have been canceled as requested. Claims 26, 37-44, and 49-53 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for second or third generation antidepressants as set forth in amended claim 37, does not reasonably provide enablement for second or third generation antidepressants outside the scope of those of amended claim 37. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors

have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to composition for local administration comprising a second or third generation antidepressant. The nature of the invention is extremely complex in that it encompasses anticipating numerous compounds outside the definition provided on page 8 of the instant specification while not defining parameters for these compounds. As such, the claims are broad.

State of the Art: The state of the art does not appear to recognize second or third generation antidepressants outside the scope of instant claim 37.

Guidance of the Specification: The guidance given by the specification regarding what constitutes and how to make second or third generation antidepressants outside those set forth in instant claim 37. Guidance for treatment of memory disorders, hyperglycemia, and skin infections is provided, however, no evidence that these conditions are prevented is provided.

The Amount of Experimentation Necessary: Although the art provides a certain level of guidance with regards to second or third generation antidepressants within the scope of those set forth in instant claim 37, these teachings do not provide sufficient guidance where the specification is lacking.

The art demonstrates locally administered compositions for those compounds within the scope of instant claim 37, but does not teach second or third generation antidepressants outside those set forth in instant claim 37. Therefore, the practitioner

would turn to trial and error experimentation to make/use the instant compositions. Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 26, 37-44, and 49-51 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Smith et al (5,922,341; hereafter '341).

'341 discloses topical antidepressant compositions for treatment of premature ejaculation (abstract; column 4, line 19-column 5, line 25; examples; claims).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 26, 37-44, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (5,922,341; hereafter '341).

'341 teaches topical antidepressant compositions for treatment of premature ejaculation (abstract; column 4, line 19-column 5, line 25; examples; claims). Manipulation of the amounts of ingredients would have been obvious to one skilled in the art at the time of the invention in an effort to increase or decrease the amount of effect.

7. Claims 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (5,922,341; hereafter '341) in view of Kitchell et al (5,486,362; hereafter '362).

'341 is relied upon for all that it teaches as stated previously. '341 does not teach encapsulation in a slow release delivery vehicle.

'362 teaches topical controlled release microsphere compositions comprising tricyclic antidepressants. The compositions of '362 are administered by local injection.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references with the motivation of providing controlled release of the compositions of '341.

Response to Amendment

8. The Declaration filed on 2-22-02 under 37 CFR 1.131 has been considered but is ineffective to overcome the '341 reference.

9. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the '341 reference or the '362 as applied under 35 USC

103(a) reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The scope of the declaration or affidavit is not commensurate with the scope of the claim(s). The declaration provides support for "first generation antidepressants" (i.e. amitriptyline), but not for second or third generation antidepressants. Furthermore, the declaration does not provide support for the limitations of instant claims 52-53 where the compositions are encapsulated in a slow release delivery vehicle such as a microsphere (significant for application to '362).

10. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the '341 reference to either a constructive reduction to practice or an actual reduction to practice. The declaration provides evidence for local administration of amitriptyline prior to October 28, 1997, however no evidence for diligence between this date and the filing date of the International Application (5-19-1999) has been provided.

Response to Arguments

11. Applicant's arguments filed 2-22-02 have been fully considered but they are not persuasive. Applicants argue that the applied references are not available as prior art

based upon the evidence provided in the Declaration under 37 CFR 1.131. However, for the reasons above, this declaration is not found persuasive.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

tw
May 20, 2002